



March 28, 2019

Via Electronic Mail Only

U.S. Department of Health and Human Services
Office of the Assistant Secretary for Health
200 Independence Ave., SW
Room 736E
Attn: Alicia Richmond Scott,
Pain Management Best Practices Inter-Agency Task Force Designated Federal Officer
Washington, DC 20201

Re: Pain Management Best Practices Inter-Agency Task Force—Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations

Dear Ms. Scott:

On behalf of the members of the Advanced Medical Technology Association (AdvaMed), we are writing to provide comments on the Draft Report on Pain Management Best Practices: Updates, Gaps, Inconsistencies, and Recommendations. AdvaMed member companies produce the medical devices, diagnostic products, and health information systems that are transforming health care. We are committed to ensuring patient access to life-saving and life-enhancing devices and other advanced medical technologies in the most appropriate settings, including innovative devices, medical applications, and diagnostic tests that treat and manage pain.

AdvaMed appreciates the efforts of the Inter-Agency Task Force in developing this draft report and appreciates the opportunity to provide comments. The opioid epidemic is taking a tremendous toll on our country and its citizens. Given the link between opioid abuse and chronic and acute pain, significant consideration should be given to advancing methods to address and alleviate these types of pain, including procedures that may reduce the level of pain experienced by patients (i.e. minimally invasive surgeries) and other evidence-based device interventions that can directly target and minimize acute and chronic pain, including invasive and non-invasive modalities such as spinal cord stimulators, implantable intraspinal drug infusion pumps, cooled and standard radiofrequency neuroablation, cryoneurolysis, electromagnetic energy, digital therapeutics, and portable continuous pain relief systems. Per FDA leadership that Agency has approved/cleared more than 200 medical device alternatives that help treat pain.

AdvaMed is dedicated to doing our part to assist in alleviating this epidemic. While the draft report does a good job in identifying many of the gaps that are perpetuating this problem, we believe that some of the recommendations can be refined to better address the role and impact of medical devices in curbing this epidemic.

Our comments will address the following issues:

- Expanded Screening and Risk Assessment
- Integration of Medical Devices and Education
- Ensuring Access

Expanded Screening and Risk Assessment

AdvaMed agrees that the adoption and use of clinical best practices and additional screening/risk assessment is imperative in curbing the opioid epidemic. This would include screening of Medicare eligible seniors per section 2002 of H.R. 6. ("SUPPORT for Patients and Communities Act"). Health care providers should be more engaged in determining, at the onset of treatment, whether a patient has the propensity to develop an opioid use disorder (OUD). AdvaMed also recommends that patients who may be at risk of OUD due to personal history, family history, or other underlying physical and psychological conditions should be immediately considered for device-based treatments that avoid the prescription and use of opioids. Additionally, insurers should be required to provide coverage and payment for use of these opioid alternative technologies at the onset of treatment instead of requiring patients to undergo a step-wise treatment approach that may start with drug therapy.

Integration of Medical Devices and Education

Health care providers must be better informed of the treatment impacts that can be gained by using non-opioid devices. This will require more education regarding the range of devices and the appropriate time for their incorporation into patient treatment plans. It will also require provider education regarding the range of available device-based treatments. While the draft report frequently highlights the role of pain and primary care physicians in the treatment of these at-risk patients, it does not mention several other physician specialists who may be involved in making recommendations to patients regarding alternative means for treating their pain. This list of physicians could include neurologists, orthopods, physical medicine, emergency medicine, anesthesiologists, physical therapists, and others.

A variety of health care providers encounter and make care decisions for patients who could potentially benefit from an opioid alternative device. Therefore, it is critical that education regarding the epidemic, appropriate screening, and treatment options (device, drug, combinations, and restorative therapy alternatives) be made known to all care providers. Additionally, it is important for care providers to have information regarding integrating these devices into the treatment process. AdvaMed agrees that this could be addressed through the integration of additional information into the medical school curriculum, including pain training in CME courses, and the dissemination and adoption of protocols and information across sites of care. The Accreditation Council for Graduate Medical Education, HHS, and physician specialty societies could also work collaboratively to develop strategies for addressing training and education shortfalls.

Patients who experience chronic pain may not seek out the care of pain physicians but instead may seek care from their primary care physician or from a physician specializing in treating the area of the body in which they are experiencing the chronic pain (e.g. a neurologist). Therefore, it is important that the full spectrum of health care providers be updated regarding the latest technologies to use in treating chronic pain. Additionally, in the context of acute pain, it is equally as important to consider the risks and outcome impacts associated with the type of surgical technique that is utilized in treating a patient's medical condition. For instance, patients may experience less post-surgical pain if treated with minimally invasive surgical procedures when appropriate. The lower pain outcomes resulting from use of these less invasive procedures could alleviate the need to prescribe opioids post-surgery.

Ensuring Access

One of the issues that AdvaMed members experience related to the deployment of opioid alternative devices is the inability of patients to access these innovations at the appropriate time. These access concerns are the result of various issues including delays in acquiring an appropriate code (e.g. CPT or HCPCS) to identify and track use of the device, disincentives in the payment system to utilize these technologies because of the low cost of potentially addictive drugs, and coverage delays which may require patients to undergo drug therapy for pain relief (posing possible addiction risk) prior to being able to utilize a device-based intervention.

AdvaMed would encourage the task force to consider recommendations to CMS and the FDA regarding code review and approval/clearance processes that recognize the necessity of bringing evidence-based opioid alternative devices to the patients that need them with minimal delay—including new devices and iterative improvements to existing devices. For example, the FDA Innovation Challenge (Challenge) was created to spur the development of medical devices, including diagnostic tests and digital health technologies (mobile medical applications) to help combat the opioid crisis and prevent and treat OUD. Challenge’s eight participants, which include some AdvaMed member companies, work directly with the FDA to accelerate development and expedited marketing application review of innovative products. AdvaMed supports Challenge and other efforts to improve the trial design, evidence, and data collection processes for innovating medical products intended to treat acute and chronic pain-- including those identified in section 3001 of HR 6 of the SUPPORT for Patients and Communities Act (SUPPORT Act).

Another way to improve access is through development of a more streamlined process to expedite placement of device-based opioid alternatives into New Technology APCs—reducing the current six month or longer process to a more reasonable time. AdvaMed appreciates the draft report highlighting these issues and urges the Inter-Agency Task Force to work with payers and other entities to implement recommendations aimed at ensuring patient access to opioid device alternatives, via consistent and timely insurance coverage, and reforming payment systems to eliminate financial incentives, which promote use of potentially addictive opioids in lieu of procedures and devices that can reduce acute and chronic pain. Specifically, we ask the Task Force to recommend that CMS implement additional payments for devices with evidence of opioid reduction and/or pain alleviation to reduce disincentives for their use, consistent with section 6082 of the SUPPORT Act. We would also recommend that any modification of the *CDC Guideline for Prescribing Opioids for Chronic Pain* include discussion regarding the use of evidence-based device alternatives.

AdvaMed is also supportive of the Task Force’s desire to include the use of e-health and mobile technologies in the treatment of pain. We would, however, caution against adopting recommendation 3b, or any similar recommendations, which limit performance of interventional pain procedures to physicians credentialed in interventional pain as several other highly-trained specialists perform these procedures in an array of patients using the devices identified in the draft report and many others.

Conclusion

AdvaMed appreciates the opportunity to provide these comments and asks that they be strongly considered by the Inter-Agency Task Force. We, along with our members, look forward to continuing to work with the Task Force and its member agencies on solutions that will help to alleviate and control the acute and chronic pain that is contributing to this nation-wide crisis. Please feel free to contact me should you have any questions at 202-434-7218 or ddorsey@advamed.org.

Sincerely,



DeChane Dorsey, Esq.
Vice President
Payment and Healthcare Delivery Policy